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Birch Stewart Kolasch & Birch LLP
P O Box 747
Falls Church, VA 22040-0747

EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/27/2002

13

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,497

Applicant(s)

KOLTERMANN ET AL.

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 09 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the kit is used to carry out the method of invention and it would not be undue burden to search. This is not found persuasive because the kit claims contain components that would be used in a plurality of other methods including sequencing and hybridization detection assays and primer extension assays. The scope of the variety methods employable by such reagents is expansive creating undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Claim 32 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 9 November 1999. It is noted, however, that applicant has not filed a certified copy of the 199 53844.9 application as required by 35 U.S.C. 119(b).

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Specification

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use. In particular, insertion of Brief Description of Drawings is recommended.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).**
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The specification is objected to because it contains hyperlinks (see page 23).

According to MPEP 608.01

Hyperlinks and Other Forms of Browser-Executable Code in the Specification

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Examiners must review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not included in a patent application. Examples of a hyperlink or a browser-executable code are a URL placed between these symbols "< >" and http: followed by a URL address. When a patent application with embedded hyperlinks and or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites.

If hyperlinks and or other forms of browser-executable code are embedded in the text of the patent application, **examiners should object to the specification** and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are **impermissible and require deletion**.

5. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

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Claim Objections

In claim 1 step a the phrase "also strands" is grammatically incorrect.

In claim 10 the term "heteroduplices" should be referred to as "heteroduplexes".

In claims 21,25 & 30 the bacterial genus-species names should be italicized. e.g. "Alteromonas espejiana".

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-31 are confusing because they are drawn to a method but no clear and defined steps are recited. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion and clearly refer back to the preamble of the claim. See ex parte Erlich, 3 USPQ2, p. 1011 (Bd. Pat. A.P. In. 1986). It is suggested that all claims be amended to set forth active steps e.g. forming, degrading, synthesizing.

B) In claim 4 the term "the region selectivity" lacks antecedent basis. It is unclear as to what is being referred to.

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C) In claim 1 the phrase "is also strands are contained that are each completely or partially complementary single strands". It is unclear as to whether separate strands or hybridized strands are being referred to.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1,4,7-9,14 & 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Brenner WO 00/14282 (16 March 2000).

Brenner teach a method for screening for genetic polymorphism. They teach providing a population of single stranded DNA polynucleotides having homologous and heterologous segments, forming double stranded heteroduplex population, degrading with partial exonucleolysis of double stranded heteroduplexes in 3'-5' direction, and performing single stranded synthesis of degraded ends (see Figure 1B & page 10). The exonucleolytic activity is controlled by the use of exonuclease. They then perform a selection step by inserting amplicons into clones to transform and identify sequences (see abstract). They teach exonuclease III from E. coli (see page 8 line 12). They teach the use of modified primers and restriction digestion leading to products with 5' end that are resistant to exonuclease activity (see page 10 lines 11-15).

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,3 & 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner WO 00/14282 (16 March 2000)

The teachings of Brenner are described previously.

Brenner do not explicitly teach performing multiple cycles.

One of ordinary skill in the art would have been motivated to multiply repeat Brenner steps of heteroduplex and amplification in order to increase the heteroduplex formation. It was well known and commonly practiced in the art to repeat cycles of amplification processes in order to increase the end product formation. Using straight forward logical reasoning, it would have been prima facie obvious to one of ordinary skill in the art to repeat the Brenner method steps in order to increase the end amplified product for detection.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner WO 00/14282 (16 March 2000) in view Weghorst et al (US6,080,544 June 27, 2000 102(e) date of 13 February 1998).

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The teachings of Brenner are described previously.

Brenner do not explicitly teach quasi species

Rice et al teach quasi species (see col. 7 line 14).

One of ordinary skill in the art would have been motivated to apply Brenner method to quasi species in order to detect viral mutants. Viral mutants at the time of the invention was made were studied to detect mutations that would affect pathology and infectivity. It would have been prima facie obvious to apply Brenner method detection to quasi species in order to detect viral mutants.

10. Claim 10,29 & 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner WO 00/14282 (16 March 2000) in view Weghorst et al (US6,080,544 June 27, 2000 102(e) date of 13 February 1998).

The teachings of Brenner are described previously.

Brenner do not teach exonuclease I from E. coli or application to RNA.

Weghorst et al teach exonuclease I (Epicenter) for digesting and single stranded polynucleotides and single stranded ends of heteroduplexes (see col. 11 lines 7-14 & figure 2A). They also teach formation of RNA-DNA heteroduplexes (see col. 1 lines 54 & col. 6 line 63). They teach the formation of reverse transcribed RNA (see col. 5 lines 45).

One of ordinary skill in the art would have been motivated to apply Weghorst et al's exonuclease I to Brenner heteroduplexes in order to maximize the heteroduplex formation. Weghorst et al states that exonuclease removes excess single stranded DNA which may produce artifactual mismatches and lead to spurious results(see col.4 lines 60). It would have been prima

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facie obvious to apply Weghorst et al's exonuclease to Brenner heteroduplexes in order to decrease artifactual mismatches.

Epicenter catalogue is provided showing that Epicenter exonuclease is E. coli derived.

11. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner WO 00/14282 (16 March 2000) in view Weghorst et al (US6,080,544 June 27, 2000 102(e) date of 13 February 1998).

The teachings and suggestions of Brenner and Weghorst et al are described previously.

Brenner do not teach M-MuLV RT.

One of ordinary skill at the time the invention was made would have been motivated to apply M-MuLV RT to Brenner and Weghorst combined method in order to reverse transcribe the RNA. It was well known and commonly practiced in the art to use M-MuLV RT to successfully reverse transcribe RNA to DNA. It would have been prima facie obvious to apply RT to Brenner and Weghorst et al's combined method in order to reverse transcribe RNA with high fidelity.

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SUMMARY

12. Claims 11-13 & 16-28 are free of the prior art but rejected under 112 second paragraph. There is no prior art that teach or suggest the claimed method of prior to partial exonucleolytic single strand degradation nicks are introduced into double strand molecules. There is no prior art that teach or suggest the claimed method of performing partial 5' to 3' exonucleolytic single strand degradation.

CONCLUSION

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.


Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.


JEFFREY SIEW
PRIMARY EXAMINER

November 24, 2002